Immunization Schedule for HIV Exposed and Infected Children and Adolescents

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ACIP meeting, June 28th, 2007

Immunization Schedules for HIV Infected Persons

- Being developed for new guidelines for prevention (and treatment) of opportunistic infections in this population
- Collaboration CDC, NIH, IDSA
- CDC requested to develop the immunization schedules

Existing Guidelines

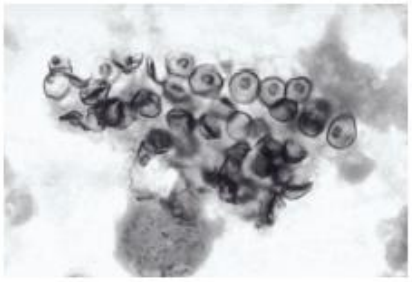
MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports — June 14, 2002 / Vol. 51 / No. RR-8

Guidelines for Preventing Opportunistic Infections Among HIV-Infected Persons — 2002

Recommendations of the U.S. Public Health Service and the Infectious Diseases Society of America



INSIDE: Continuing Education Examination

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MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports — December 17, 2004 / Vol. 53 / No. RR-15

Treating Opportunistic Infections Among HIV-Infected Adults and Adolescents

Recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association/ Infectious Diseases Society of America

MMWR

Morbidity and Mortality Weekly Report

Recommendations and Reports — December 3, 2004 / Vol. 53 / No. RR-14

Treating Opportunistic Infections Among HIV-Exposed and Infected Children

Recommendations from CDC, the National Institutes of Health, and the Infectious Diseases Society of America

New Guidelines for Prevention & Treatment Opportunistic Infections in HIV Infected Persons

- Guidelines for HIV Infected Children
  - Vaccine schedules 0-6 year and 7-18 years
- Guidelines for HIV+ Adults
  - Vaccine schedule adults
- Publication expected sometime in the fall but “living documents” which will be updated on the web

Approach to Developing Schedules

- Starting point: published 2007 schedules for 0-6 years, 7-18 years and adults
- Used published ACIP recommendations for specific language for HIV infected persons
- Clarified footnote language, if needed, in discussion with CDC SMEs
- Bars:
  - 0-6 schedule: removed catch up bars
  - If HIV were the high risk group, bars purple to yellow (routinely recommended)

Approach to Developing Schedules

- Draft schedules shared with CDC, NIH, IDSA working group (meeting NIH June 25-26)
- Presented to ACIP Harmonized Working Group who suggested ACIP vote
- No plans to harmonize with AAP, AAFP

ACIP Rotavirus Vaccine Statement

- No safety or efficacy data are available for the adminstration of rotavirus vaccine to infants who are potentially immunocompromised including infants with HIV

- Data are insufficient from the clinical trials to support administration of rotavirus vaccine to infants with indeterminant HIV status who are born to mothers with HIV/AIDS

- Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with known or suspected altered immunocompetence

HIV Child Schedule Footnote

- No safety or efficacy data are available for the administration of rotavirus vaccine to infants who are potentially immunocompromised including infants with HIV

- However, the following considerations support vaccination of HIV infected infants
  - 1) HIV diagnosis may not be established before the age of the first rotavirus vaccine dose
  - 2) immunosuppression is minimal in the immediate months after birth
  - 3) Rotavirus disease could be more severe in HIV+ infants

Scientific Issues: 1

- 6,000 – 7,000 HIV exposed infants are born each year in the US. HIV status will not be definitively known by 6 weeks but most will be presumptively negative. Only ~ 100-200 will eventually test positive
- Rotavirus is a ubiquitous infection in childhood
- Rotateq vaccine strain is considerably attenuated with low incidence of fever, other constitutional Sxs, oral shedding
- Available data suggesting rotavirus disease is not more severe in HIV+ infants
- Study in Malawi showed higher all cause mortality in HIV infected children during 4 weeks of follow up after RV illness [22% (11/50) vs 0% (0/61)]. Significance?
- More data are needed on disease severity in older, more Immunosuppressed HIV + children

Scientific Issues: 2

- OPV replicates more robustly in intestinal tract (with much higher shedding risk) than Rotateq and is considered to be safe and immunogenic in HIV+ children
  - Ryder et al, J Pediatr 1993, Zaire No safety concerns, >95% developed protective levels to all 3 PVs
  - No increased risk VAPP (Bull WHO 2003; 81: 61-70)
- No trials with rotavirus vaccine are planned for the US in HIV+ infants
- Issues are different in developing countries where numbers of HIV infected children are higher, co-morbidities are common (especially malnutrition) and disease burden & mortality from rotavirus disease is high
- Trials with GSK & Merck vaccine underway/planned

HIV Child Schedule Footnote (revised)

- No safety or efficacy data are available for the adminsitration of rotavirus vaccine to infants who are potentially immunocompromised including infants with HIV

- However, the following considerations support vaccination of HIV infected infants
  - 1) HIV diagnosis may not be established before the age of the first rotavirus vaccine dose. Only 1.5% - 3% of HIV exposed infants in the US will eventually test HIV positive
  - 2)Natural rotavirus infection does not appear to be more severe in HIV-infected infants
  - 3) Rotateq vaccine is considerably attenuated

Recommended Immunization Schedule for HIV Infected Children Aged 0–6 Years—UNITED STATES • 2007

Vaccine ▼ / Age ►	Birth	1 month	2 months	4 months	6 months	12 months	13 months	15 months	18 months	19–23 months	2–3 years	4–6 years
Hepatitis B[1]	HepB	HepB		see footnote 1	HepB							
Rotavirus[2]			Rota	Rota	Rota							
Diphtheria, Tetanus, Pertussis[3]			DTaP	DTaP	DTaP			DTaP				DTaP
Haemophilus influenzae type b[4]			Hib	Hib	*Hib*[4]	Hib						
Pneumococcal[5]			PCV	PCV	PCV	PCV					PPV	
Inactivated Poliovirus			IPV	IPV	IPV							IPV
Influenza[6]					TIV (Yearly)							
Measles, Mumps, Rubella[7]						MMR	MMR					
						Do not administer to severely immunosupressed (CD4% T-lymphocyte count <15%) children						
Varicella[8]						Varicella		Varicella				
						Do not administer to severely immunosupressed (CD4% T-lymphocyte count <15%) children						
Hepatitis A[9]						HepA (2 doses)					HepA Series	
Meningococcal[10]											MPSV4	

Range of recommended ages for vaccination

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2006, for **HIV infected children aged 0–6 years**. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended after this immunization schedule is published. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at **http://www.vaers, hhs.gov** or by telephone, **800-822-7967**.

Recommended Immunization Schedule for HIV Infected Children Aged 0–6 Years—UNITED STATES • 2007

FOOTNOTES

1. Hepatitis B vaccine (HepB). *(Minimum age: birth)*

At birth:
- Administer monovalent HepB to all newborns before hospital discharge.
- If mother is hepatitis surface antigen (HBsAg)-positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
- If mother's HBsAg status is unknown, administer HepB within 12 hours of birth. Determine the HBsAg status as soon as possible and if HBsAg-positive, administer HBIG (no later than age 1 week).
- If mother is HBsAg-negative, the birth dose can only be delayed with physician's order and mother's negative HBsAg laboratory report documented in the infant's medical record.

After the birth dose:
- The HepB series should be completed with either monovalent HepB or a combination vaccine containing HepB. The second dose should be administered at age 1–2 months. The final dose should be administered at age ≥24 weeks. Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg after completion of ≥3 doses of a licensed HepB series, at age 9–18 months (generally at the next well-child visit).

4-month dose:
- It is permissible to administer 4 doses of HepB when combination vaccines are administered after the birth dose. If monovalent HepB is used for doses after the birth dose, a dose at age 4 months is not needed.

Post vaccination:
- Testing is recommended for HIV-infected children and should be performed 1–2 months after administration of the last dose of the vaccine series using a method that allows determination of a protective level of anti-HBs (≥10mIU/mL).
- Persons found to have anti-HBs levels of <10 mIU/mL after the primary series should be revaccinated. Administration of 3 doses on an appropriate schedule followed by anti-HBs testing 1–2 months after the 3rd dose is usually more practical than serologic testing after one or more doses of vaccine.

Booster dose:
- In HIV infected children, the need for booster doses has not been determined. Annual antiHBs testing and booster doses when anti-HBs levels decline to <10 mIU/mL should be considered in persons with ongoing risk of exposure. See *MMWR* 2005:54 [No. RR-16]:1–23.

2. Rotavirus vaccine (Rota). *(Minimum age: 6 weeks)*

No safety or efficacy data are available for the administration of rotavirus vaccine to infants who are potentially immunocompromised, including those who are HIV-positive. However, the following considerations support vaccination of HIV infected infants: **1)** the HIV diagnosis may not be established in infants born to HIV positive mothers before the age of the first rotavirus vaccine dose, **2)** the immunosuppression is minimal in the immediate months after birth and **3)** rotavirus disease could be more severe in HIV infected compared to normal infants.
- Administer the first dose at age 6–12 weeks. Do not start the series later than age 12 weeks.
- Administer the final dose in the series by age 32 weeks. Do not administer a dose later than age 32 weeks.
- Data on safety and efficacy outside of these age ranges are insufficient.

3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). *(Minimum age: 6 weeks)*
- The fourth dose of DTaP may be administered as early as age 12 months, provided 6 months have elapsed since the third dose.
- Administer the final dose in the series at age 4–6 years.

4. *Haemophilus influenzae* type b conjugate vaccine (Hib). *(Minimum age: 6 weeks)*
- If PRP-OMP (PedvaxHIB® or ComVax® [Merck]) is administered at ages 2 and 4 months, a dose at age 6 months is not required.
- TriHiBit® (DTaP/Hib) combination products should not be used for primary immunization but can be used as boosters following any Hib vaccine in children aged ≥12 months.
- Clinicians and other health-care providers might consider use of Hib vaccine among children with HIV infection older than 59 months who did not receive the vaccine as an infant or in childhood. See *MMWR* 2006:55 [No. RR-15].

5. Pneumococcal vaccine. *(Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPV])*
- Heptavalent pneumococcal conjugate vaccine (PCV) is recommended for all HIV-infected children aged 2-59 months.
- Children aged ≥2 years should also receive the 23-valent pneumococcal polysaccharide vaccine; a single revaccination with the 23-valent vaccine should be offered to children after 3–5 years. For dosing intervals for children starting the vaccination schedule after age 2 months. See *MMWR* 2000;49 [No. RR-9]:1–35.

6. Influenza vaccine. *(Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 5 years for live, attenuated influenza vaccine [LAIV])*
- All HIV infected children aged 6 months through 6 years and close contacts (including household members) of these children are recommended to receive influenza vaccine each year. Only TIV should be used for HIV-infected children.
- For healthy close contacts aged 5–49 years, LAIV may be used as an alternative to TIV.
- Children receiving TIV should receive 0.25 mL if aged 6–35 months or 0.5 mL if aged ≥3 years.
- Children aged <9 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by ≥4 weeks for TIV). See *MMWR* 2006;55 [No. RR-10]:1–48.

7. Measles, mumps, and rubella vaccine (MMR). *(Minimum age: 12 months)*
- MMR vaccine is recommended for all asymptomatic HIV-infected children who are not severely immunosuppressed (CD4% T-lymphocyte count ≥15%) and who lack evidence of measles immunity.
- MMR vaccine for symptomatic HIV-infected children should be considered if they **a)** do not have evidence of severe immunosuppression (CD4% T-lymphocyte count ≥15%) and **b)** lack evidence of measles immunity.
- The first dose of MMR vaccine should be administered as soon as possible after the first birthday. Consideration should be given to administering the second dose 1 month (i.e., a minimum of 28 days) after the first dose rather then waiting until age 4 to 6 years.
- MMRV vaccine has not been studied in HIV infected children and should not be substituted for MMR vaccine.
- MMR and other measles-containing vaccines are not recommended for HIV-infected children with evidence of severe immunosuppression (CD4% T-lymphocyte count <15%). See *MMWR* 1998;47 [No. RR-8]:1–67, Table 2: Special Considerations for Vaccination—Persons Infected with Human Immunodeficiency Virus [HIV]).

8. Varicella vaccine. *(Minimum age: 12 months)*

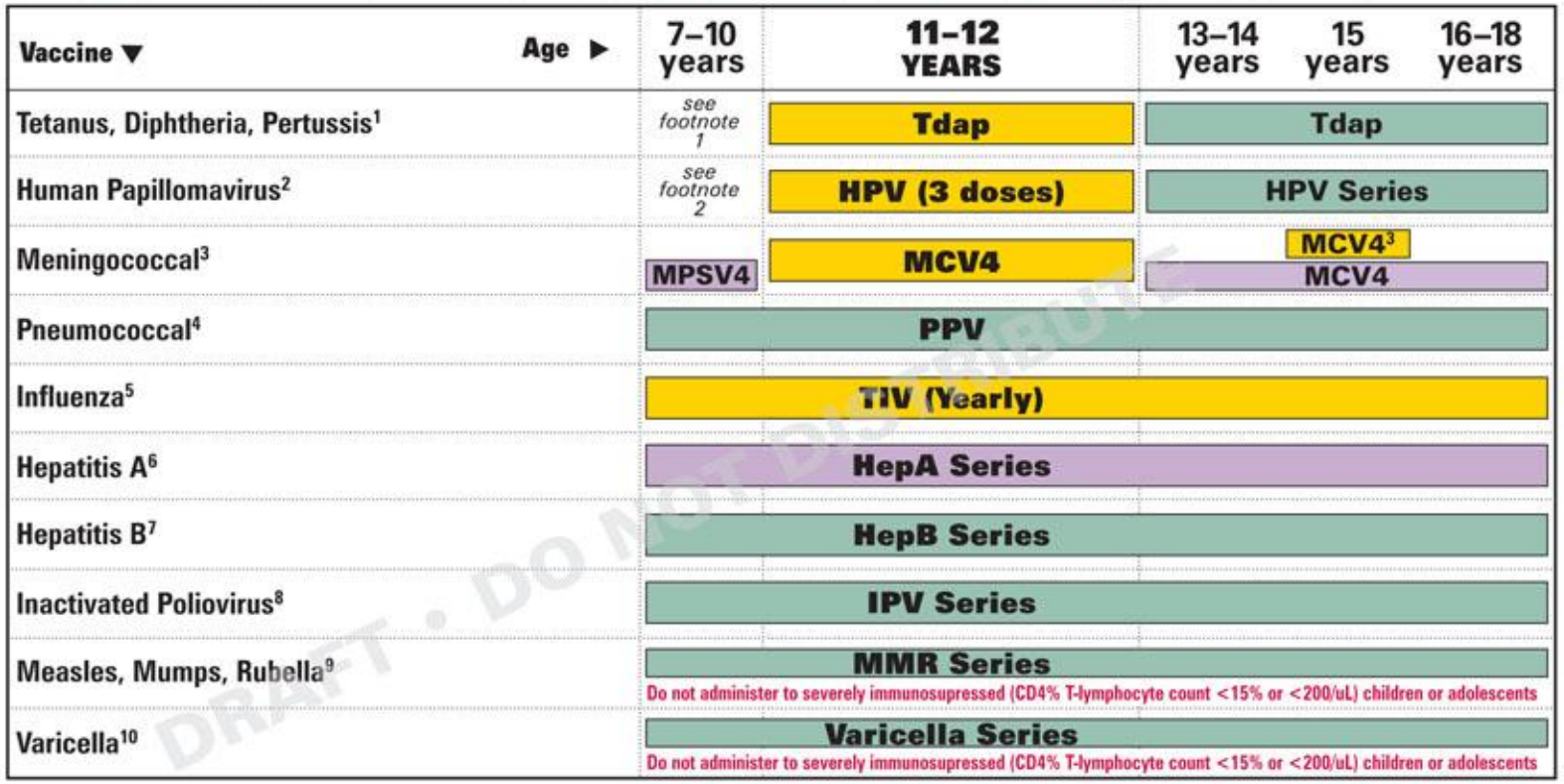
Limited data are available on safety and immunogenicity of varicella vaccine in HIV infected children 1–8 years in CDC immunological categories 1 and 2 (CD4+ T-lymphocyte percentage ≥15%) and clinical categories N, A and B.
- Single antigen varicella vaccine should be considered for HIV-infected children with CD4% T-lymphocyte count ≥15%. Eligible children should receive 2 doses 3 months apart with the first dose administered as soon as possible after the first birthday.
- MMRV vaccine has not been studied in HIV infected children and should not be substituted for single antigen varicella vaccine.
- Varicella vaccines is not recommended for HIV-infected children with evidence of severe immunosuppression (CD4% T-lymphocyte count <15%). See *MMWR*, 2007;56 [No. RR-4]:1–40.

9. Hepatitis A vaccine (HepA). *(Minimum age: 12 months)*
- HepA is recommended for all children aged 1 year (i.e., aged 12–23 months). The 2 doses in the series should be administered at least 6 months apart.
- Children not fully vaccinated by age 2 years can be vaccinated at subsequent visits.
- HepA is recommended for certain other groups of children including in areas where vaccination programs target older children. See *MMWR* 2006;55 [No. RR-7]:1–23.

10. Meningococcal polysaccharide vaccine (MPSV4). *(Minimum age: 2 years)*
- Administer MPSV4 to children aged 2–6 years with terminal complement deficiencies or anatomic or functional asplenia and certain high risk groups. Children with HIV are likely at increased risk for meningococcal disease although not to the extent that they are at risk for invasive *S. pneumoniae* infection. Although the efficacy of MPSV4 among HIV-infected children is unknown, HIV-infected children that do not fit into the above groups may elect vaccination. See *MMWR* 2005;54 [No. RR-7]:1–21.

FOR MORE INFORMATION SEE THE CATCH-UP SCHEDULE

Recommended Immunization Schedule for HIV Infected Children Aged 7–18 Years—UNITED STATES • 2007



This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2006, for **HIV infected children and adolescents aged 7–18 years**. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended after this immunization schedule is published. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at **http://www.vaers, hhs.gov** or by telephone, **800-822-7967**.

Recommended Immunization Schedule for HIV Infected Children Aged 7–18 Years—UNITED STATES • 2007

FOOTNOTES

1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap). *(Minimum age: 10 years for BOOSTRIX® and 11 years for ADACEL™)*

- Administer at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoids vaccine (Td) booster dose.
- Adolescents aged 13–18 years who missed the 11–12 year Td/Tdap booster dose should also receive a single dose of Tdap if they have completed the recommended childhood DTP/DTaP vaccination series.

2. Human papillomavirus vaccine (HPV). *(Minimum age: 9 years)*

No data are available on immunogenicity, safety and efficacy of HPV vaccine in HIV-infected persons. However, because quadrivalent HPV vaccine is a noninfectious vaccine, it can be administered to females who are immunosuppressed as a result of disease or medications including HIV infected females. However, the immune response and vaccine efficacy might be less than that in persons who are immunocompetent. See *MMWR* 2007;56 [No. RR-2] and *MMWR* 2006:55 [No. RR-15]. Studies are ongoing in HIV infected females.

- Administer the first dose of the HPV vaccine series to females at age 11–12 years.
- Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose.
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

3. Meningococcal vaccine. *(Minimum age: 11 years for meningococcal conjugate vaccine [MCV4]; 2 years for meningococcal polysaccharide vaccine [MPSV4])*

- Administer MCV4 at age 11–12 years and to previously unvaccinated adolescents at high school entry (at approximately age 15 years).
- Administer MCV4 to previously unvaccinated college freshmen living in dormitories; MPSV4 is an acceptable alternative.
- Vaccination against invasive meningococcal disease is recommended for children and adolescents aged ≥2 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups. See *MMWR* 2005;54 [No. RR-7]:1–21. Use MPSV4 for children aged 2–10 years and MCV4 or MPSV4 for older children.
- Patients with HIV are likely at increased risk for meningococcal disease although not to the extent that they are at risk for invasive *S. pneumoniae* infection. Although the efficacy of MCV4 among HIV-infected patients is unknown, HIV-infected patients 11–18 years that do not fit into the above groups may elect vaccination. For persons 11–18 years who have been previously vaccinated with MPSV4, revaccination with MCV4 is not indicated unless vaccination occurred 3-5 years previously and the person still remains at increased risk for meningococcal disease. For revaccination recommendations. See *MMWR* 2005;54 [No. RR-7]:1–21.

4. Pneumococcal polysaccharide vaccine (PPV). *(Minimum age: 2 years)*

- If not previously vaccinated, children and adolescents aged 7-18 years should receive the 23-valent pneumococcal polysaccharide vaccine; a single revaccination with the 23-valent vaccine should be offered after 3-5 years. See *MMWR* 1997;46 [No. RR-8]:1–24, and *MMWR* 2000;49 [No. RR-9]:1–35.

5. Influenza vaccine. *(Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]); 5 years for live, attenuated influenza vaccine [LAIV])*

- Influenza vaccine is recommended annually for HIV-infected children and adolescents 7–18 years and their close contacts (including household members). Only TIV should be used for HIV-infected persons.
- For healthy close contacts aged 5–49 years, LAIV may be used as an alternative to TIV.
- Children aged <9 years who are receiving influenza vaccine for the first time should receive 2 doses (separated by ≥4 weeks for TIV and ≥6 weeks for LAIV). See *MMWR* 2006;55 [No. RR-10]:1–41.

6. Hepatitis A vaccine (HepA). *(Minimum age: 12 months)*

- The 2 doses in the series should be administered at least 6 months apart.
- HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children. See *MMWR* 2006;55 [No. RR-7]:1–23.

7. Hepatitis B vaccine (HepB). *(Minimum age: birth)*

- Administer the 3-dose series to those who were not previously vaccinated.
- Post vaccination testing is recommended for HIV-infected persons. Testing should be performed 1–2 months after administration of the last dose of the vaccine series using a method that allows determination of a protective level of anti-HBs (≥10mIU/mL). Persons found to have anti-HBs levels of <10 mIU/mL after the primary series should be revaccinated. Administration of 3 doses on an appropriate schedule followed by anti-HBs testing 1–2 months after the 3rd dose is usually more practical than serologic testing after one or more doses of vaccine. Modified dosing regimens, including a doubling of the standard antigen dose might increase response rates. However, data on response to these alternative vaccination schedules are limited.
- In HIV infected persons, the need for booster doses has not been determined. Annual antiHBs testing and booster doses when anti-HBs levels decline to <10 mIU/mL should be considered in persons with ongoing risk of exposure.

8. Inactivated poliovirus vaccine (IPV). *(Minimum age: 6 weeks)*

- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age ≥4 years.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

9. Measles, mumps, and rubella vaccine (MMR). *(Minimum age: 12 months)*

- If not previously vaccinated and eligible, administer 2 doses of MMR vaccine during any visit, with ≥4 weeks between the doses.
- MMR vaccine is recommended for all asymptomatic HIV-infected children and adolescents who are not severely immunosuppressed (CD4% T-lymphocyte count ≥15% or ≥200/uL) and who lack evidence of measles immunity.
- MMR vaccine for symptomatic HIV-infected children and adolescents should be considered if they **a)** do not have evidence of severe immunosuppression (CD4% T-lymphocyte count ≥15% or ≥200 T-lymphocytes/uL) and **b)** lack evidence of measles immunity.
- MMRV vaccine has not been studied in HIV infected children and should not be substituted for MMR vaccine.
- MMR and other measles-containing vaccines are not recommended for HIV-infected children with evidence of severe immunosuppression (CD4% T-lymphocyte count <15% or <200/uL). See *MMWR* 1998;47 [No. RR-8]:1-67, Special Considerations for Vaccination—Persons Infected with Human Immunodeficiency Virus [HIV]) (Table 2).

10. Varicella vaccine. *(Minimum age: 12 months)*

- Limited data are available on safety and immunogenicity of varicella vaccine in HIV infected children 1–8 years in CDC immunological categories 1 and 2 CD4% T-lymphocyte count ≥15% and clinical categories N, A and B. Single antigen varicella vaccine should be considered for HIV-infected children 7–8 years without evidence of immunity with CD4% T-lymphocyte count ≥15% or >200 T-lymphocytes/uL. Eligible children should receive 2 doses 3 months apart.
- Data on use of varicella vaccine in HIV-infected children >8 years and adolescents is lacking. However, on the basis of expert opinion, the safety of varicella vaccine in HIV-infected persons aged >8 years with similar levels of immune function (CD4% T-lymphocyte count ≥200/uL) is likely to be similar to that of children aged <8 years. Immunogenicity might be lower in HIV-infected adolescents (and adults). However, weighing the risk for severe disease from wild VZV and potential benefit of vaccination, vaccination (2 doses administered 3 months apart) for persons 9 to 18 years without evidence of immunity may be considered.
- MMRV vaccine has not been studied in HIV infected children and should not be substituted for single antigen varicella vaccine.
- Varicella vaccines is not recommended for HIV-infected children or adolescents with evidence of severe immunosuppression (CD4% T-lymphocyte count <15%).
- For evidence of immunity guidance and other details, see *MMWR* 2007;56 [No.RR-4]:1–40.

11. Hib vaccine. *(Minimum age: 6 weeks)*

Hib conjugate vaccines are available in single or combined antigen preparations. Hib vaccine is recommended routinely for all children through age 59 months. Clinicians and other health-care providers might consider use of Hib vaccine among persons >59 months with HIV infection who did not receive the vaccine as an infant or in childhood. See *MMWR* 2006:55 [No. RR-15].

FOR MORE INFORMATION SEE THE CATCH-UP SCHEDULE

ACIP Vote

- ACIP approves the immunization schedules for HIV infected children 0-6 years and 7-18 years

- New ACIP recommendations will be incorporated into the schedule after publication of provisional ACIP recommendations

Options for Rotavirus Vaccine Language

1. Adopt new language (with revisions as suggested)

2. Use exact ACIP statement language

   (weigh risk and benefits)

3. Recommend that vaccine not be administered until safety and immunogenicity/efficacy data are available (remove bars from schedule)

HIV Child Schedule Footnote (revised)

- No safety or efficacy data are available for the adminsitration of rotavirus vaccine to infants who are potentially immunocompromised including infants with HIV

- However, the following considerations support vaccination of HIV infected infants
  - 1) HIV diagnosis may not be established before the age of the first rotavirus vaccine dose. Only 1.5% - 3% of HIV exposed infants in the US will eventually test HIV positive
  - 2)Natural rotavirus infection does not appear to be more severe in HIV-infected infants
  - 3) Rotateq vaccine is considerably attenuated

Alternative Rotavirus Language

- No safety or efficacy data are available for the adminstration of rotavirus vaccine to infants who are potentially immunocompromised including infants with HIV
- Data are insufficient from the clinical trials to support administration of rotavirus vaccine to infants with indeterminant HIV status who are born to mothers with HIV/AIDS
- Practitioners should consider the potential risks and benefits of administering rotavirus vaccine to infants with known or suspected altered immunocompetence